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Economic Evaluation of the Use of Drug-Eluting Stents versus Bare-Metal Stents in Adults with Ischemic Cardiomyopathy Requiring Angioplasty

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ABSTRACT

Background: The value of drug-eluting stents in preventing cardiovascular events has not been investigated in Mexico. **Objective:** To conduct a cost-effectiveness analysis of early and new-generation drug-eluting stents from the perspective of a healthcare provider. **Methods:** We conducted a cost-effectiveness analysis of early and new-generation drug-eluting stents in patients with ischemic cardiomyopathy attending a Cardiology Hospital of the Mexican Social Security Institute. The health endpoint used was major acute cardiovascular events prevented. The effectiveness by stent type was obtained from the literature. A retrospective chart review study was conducted to collect cost data on cardiovascular events including seven cost categories. Average and incremental cost-effectiveness ratios were estimated. Deterministic and probabilistic sensitivity analyses were performed to test the robustness of estimates. **Results:** Incremental cost-effectiveness ratios in base-case were 28,910 and US$ 35,590 for early and new-generation stents, respectively. In an optimal scenario, incremental-cost effectiveness ratio was 24,776 and US$ 25,262 for early and new stents, respectively. Probabilistic sensitivity analysis suggested that 90% of cases were cost-effective when willingness-to-pay was 58,000 and US$ 66,000 for early and new-generation stents, respectively. **Conclusions:** The cost-effectiveness ratios of early and new-generation stents were significantly higher than corresponding bare-metal stents. (REV INVES CLIN. 2015;67:219-26)

Key words: Cost effectiveness. Bare-metal stent. Drug-eluting stent. Social security. Angioplasty.

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INTRODUCTION

Cardiovascular diseases are the main cause of morbidity and mortality in Mexico and worldwide. Cardiovascular diseases are increasing in Mexico, with an annual growth rate of 4% over the last 10 years[1]. The treatment of coronary artery disease has changed significantly since the introduction of coronary angioplasty and the later introduction of coronary stents[2]. Early generation drug-eluting stents (EGDES) had stainless steel platforms of durable polymers and released antiproliferative agents such as sirolimus or paclitaxel. Early-generation bare-metal stents (BMS) had stainless steel structures and did not release antiproliferative agents[2-4]. The development of stent technology has resulted in the new-generation drug-eluting stents (NGDES). These stents contain cobalt-chrome or platinum-chrome platforms with thinner strut thickness and more biocompatible, durable polymer coatings that release the antiproliferative agents everolimus (Xience, Promus Element™, Boston Scientific, Natick, Massachusetts) or zotarolimus (Endeavour® Resolute, Medtronic Inc., Mineapolis)[5,6]. There is a new generation of BMSs that have the same cobalt-chrome or platinum-chrome platforms but do not release antiproliferative agents[4]. In this study, we focused on BMSs, EGDESs, and NGDESs, which are available for use in angioplasty at the Cardiology Hospital at the Centro Médico Siglo XXI (CMNSXXI) of the Mexican Social Security Institute (Instituto Mexicano del Seguro Social, IMSS).

The benefits of stent angioplasty are usually observed during the first year of an acute event[4,7]. However, different outcomes may occur and may be used as efficacy or effectiveness measurements, including myocardial infarction rates, target-lesion revascularization rates, target revascularization angiographic restenosis or intra-stent restenosis, and cardiovascular death[8]. One of the issues regarding the economic value of the different stent types is the wide variation of their costs, and efficacy (or effectiveness) estimates[7]. A review of economic studies suggests that evidence is not available for Mexico. Therefore, the aim of this investigation was to conduct a cost-effectiveness analysis on the EGDESs and NGDESs through a comparison with BMSs.

METHODS

Study design and definitions

A cost-effectiveness analysis was conducted to compare EGDESs and NGDESs with BMSs during a one-year period in patients who had suffered an ischemic cardiomyopathy and underwent angioplasty with the implantation of one of the stent types described above. The study was conducted from the perspective of the health services provider. In the analysis we included the costs of the stent used in the initial percutaneous coronary intervention (PCI) and the costs of subsequent major adverse cardiac events (MACE). Other associated costs of the initial PCI were not included. The costs of MACEs were related with those for the cardiovascular event after the first angioplasty and during the first year of follow-up. A deterministic decision tree model was used to estimate the expected value of the stent alternatives. A deterministic sensitivity analysis was conducted by considering three different scenarios: best/worst and threshold analysis. In addition, we conducted a probabilistic sensitivity analysis to verify the effects of varying the parameters included in the base-case estimate and result consistency.

The effectiveness measure, which was defined as MACEs prevented during the first year of follow-up after the angioplasty, included the occurrence of: (i) angina, (ii) acute myocardial infarction, (iii) intra-stent restenosis, (iv) stent thrombosis, and (v) death from a cardiovascular cause.

To identify the risks of MACEs for each stent alternative, we conducted a systematic review of the literature reporting information on the effect size of the EGDESs and NGDESs with the outcomes used in our research. The databases searched were PubMed, the health virtual library of the Pan-American Health Organization, and LILACS (Literatura Latino-Americana y del Caribe en Ciencias de la Salud). A search period from January 2000 to August 2014 was used. Country income and settings were not imposed as restrictions for retrieving studies. Searches were performed using the following terms: stents, drug-eluting stents, bare-metal stents, sirolimus, paclitaxel, and everolimus. Searches were conducted in English and Spanish. We selected the systematic reviews with meta-analyses reporting the risk of suffering MACEs and the confidence intervals to apply the cost-effectiveness, deterministic sensitivity, and probabilistic sensitivity analyses.

Study population

We conducted a retrospective observational study consisting of a review of medical records to collect

information regarding the resource utilization of medical treatments in events that occurred after the angioplasty. The study period lasted for one year post-PCI. The protocol was approved by the hospital's local board of research. Medical consent was not required from the patients because the study was based on a review of medical records.

We reviewed a sample of the clinical records of patients with myocardial revascularization using EGDES or BMS implantation during the period between March 2007 and January 2008. Cost data were extracted from the clinical records in a questionnaire designed for this purpose. A nurse visited the hospital to complete the corresponding questionnaire. Medical records were selected in a time consecutive order based on a list of patients treated in the hospital during the study period.

The inclusion criteria for selecting the records were: (i) the patients must be > 18 and < 78 years of age, and (ii) the patients must have an ischemic cardiomyopathy with an indication of PCI with one or several injured vessels. The clinical entities included were previous (≥ 30 days) or recent (< 30 days) myocardial infarction and chronic angina stable or unstable). Exclusion criteria were: (i) patients with cardiogenic shock or patients who required rescue angioplasty, and (ii) patients whose files did not fulfill the inclusion criteria and/or had medical files that were not complete or were not located.

Costs analysis

A database was created with codes for each of the inputs used, and the costs were appraised for each patient to estimate the average cost for the sample of patients. The cost included only those costs related with MACEs during a follow-up period of one year and the stent costs. The cost of the initial PCI was not included as part of the stent-alternatives costs because this procedure is identical. The only cost that was variable for each alternative was the cost of the stent. For this reason, we included only the cost of the stent, which may be different for each alternative. The costs of the MACEs were estimated based on the following cost categories: (i) laboratory and X-ray tests; (ii) consultation visits (cardiology and other specialties); (iii) hospitalization; (iv) emergency room visits; (v) coronary intensive care unit; and (vi) other diagnostic procedures and cardiovascular interventions.

Unitary prices for the goods and services included in the costs were obtained from the official list of prices of the IMSS for 2013[9]. The unitary costs of stents were obtained from the IMSS public information database on purchased goods and services of the organization (Table 1). This database shows the unitary prices classified by stent type[10]. The EGDES and BMS costs correspond to 2006 and were updated for 2014. The NGDES costs were obtained from recent information on acquisitions at the IMSS and are available as public information[10]. All costs were reported in US dollars (US$; 2014). To translate Mexican pesos to US$, we used the average exchange rate (Mexican pesos per 1 US$) for the month of June 2014[11]. To update to 2014 prices, we used the national consumer price index for the healthcare sector[12]. We did not discount costs or outcomes because the study was conducted over a one-year time period.

The costs of each stent alternative were integrated as the sum of the initial stent and the weighted costs of the MACE. The weighted cost of a MACE was estimated as the cost of a MACE multiplied by the probability of avoiding one MACE (estimated as one probability of the occurrence of a MACE in each alternative). We estimated the average cost-effectiveness ratios and incremental cost-effectiveness ratios. Average cost-effectiveness ratios were obtained by dividing the expected costs by the probability of avoiding one MACE for each alternative. Incremental cost-effectiveness ratios were calculated by dividing the additional cost of the evaluated alternative (EGDESs or NGDESs) compared with BMSs divided by the difference in effectiveness. An average cost-effectiveness ratio is interpreted as the cost of avoiding one MACE by the corresponding alternative, and an incremental cost-effectiveness ratio is interpreted as the cost per additional MACE of EGDESs or NGDESs compared with BMSs.

The deterministic sensitivity analysis consisted of one-way worst- and best-case scenarios for determining the effect of changes in the risk of having a MACE. The scenarios were estimated considering the lower and upper values of the risk of a MACE. In addition, we estimated the threshold value of the probability of avoiding one MACE for the NGDESs, which refers to the situation when the incremental cost-effectiveness ratio of the two DES types is the same. The values of these analyses were reported as new incremental cost-effectiveness ratios for each scenario for the

Table 1. Costs of stents of initial angioplasty (pondered by average number of stents) and costs of major adverse cardiac events by initial stent type group[1]

Costs of stents of initial angioplasty*				
Type of stent	**Number stents**	**Unitary costs**	**Costs in base case (SA values)†**	**Source**
Stainless steel stent (BMS)	1.36	$ 666	$ 906 (840-979)	Own estimates from costs reported in costing study and IMSS[10]
Stainless steel DES (sirolimus, paclitaxel) (EGDES)	1.32	$ 2,230	$ 2,943 (2,631-3,277)	
Titanium-nickel or chrome cobalt cover DES (everolimus) (NGDES)	1.32	$ 2,757	$ 3,640 (3,254-4,053)	

Costs of MACE based on stent type				
Cost category†	**BMS (n = 20)**		**EGDES (n = 10)**	
	Base-case (average)	**95% confidence interval**	**Base-case (average)**	**95% confidence interval**
Specialist consultation	484	393 -575	426	383-470
Laboratory and X-ray	180	102-257	75	40-110
Hospitalization	3,721	2,449-4,994	5,873	3,606-8,140
Intensive therapy	3,130	1,018-5,242	2,087	518-3,655
Emergency room	62	25-98	89	9-168
Diagnostic and cardiology intervention procedures	1,194	953-3,035	1,907	1,317-2,497
Total costs per MACE episode†	9,571	6,754-12,388	10,456	8,895-12,018

*The total number of followed patients in the observational study was 216, 128 in the BMS group and 88 in the EGDES group. Thirty patients suffered a major acute cardiovascular event.
†Costs are in US$ (2014). The t-test value for the mean difference of two samples with different standard deviations was not significant (p = 0.78).
BMS: bare-metal stent; DES: drug-eluting stent; EGDES: early-generation drug-eluting stent; NGDES: new-generation drug-eluting stent; MACE: major adverse cardiac event.

alternatives, considering BMSs as a comparator. A probabilistic sensitivity analysis was conducted to determine the effect on the base-case cost-effectiveness estimates and to test the robustness of the model, considering the variation of all parameters in the analysis.

The strategies to determine the upper and lower values of the MACE risks for each alternative were defined as follows: the risk of the BMS was assumed to vary within ± 20% because information on the credible interval from the meta-analysis was not reported[13]. The corresponding values for EGDESs and NGDESs were assumed based on previous studies reporting credible intervals of MACE risks. We made assumptions when we believed that the values reported were not appropriate[14-17]. To conduct the probabilistic sensitivity analysis, we used a normal distribution for MACE risk and a gamma distribution for the costs. A Monte Carlo simulation was conducted considering 1,000 iterations, and the results were used to construct cost-effectiveness acceptability curves for EGDESs vs. BMSs and NGDESs vs. BMSs. All calculations were performed using Excel® 2010.

RESULTS

Several systematic reviews were identified by literature searches[5,8,13,15-19]. The risks of having a MACE for the three types of stents included in the evaluation were determined based on the results from three systematic reviews[13,15,17] (Table 2).

The BMSs group was on average older and included a slightly larger percentage of women. This group had a larger percentage of patients with diabetes, hypertension and dyslipidemia, and smokers. However, differences in these variables between groups seemed to be not significant (Table 3). Also, there were no significant differences between groups regarding other clinical variables of the population in the costs study, such as stent indication, number of stents, and number of vessels treated.

Cost results showed that the average treatment cost of one MACE was slightly higher for the EGDES group when compared with that of the BMS groups (Table 1).

Table 2. Mayor adverse event risks and their variability in patients with PCI

Cardiovascular event risk in one year period			
Type of stent	**Base-case value**	**95% confidence interval**	**Reference**
Stainless steel stent (BMS)	0.1900	0.1775-0.2144	Roiron, et al.[13]
Stainless steel DES (sirolimus, paclitaxel) (EGDEG)	0.0904	0.0783-0.1013	Babapulle, et al.[15]
Titanium/nickel or chrome/cobalt cover DES (everolimus, zotarolimus) (NGDES)	0.0764	0.0410-0.0917	Park, et al.[17]

BMS: bare-metal stent; DES: drug-eluting stent; EGDES: early-generation drug-eluting stent; NGDES: new-generation drug-eluting stent.

Table 3. Patient characteristics at initial time of follow-up in the cost analysis

Patient characteristics	Bare metal stent (n = 128)	Drug-eluting stent (n = 88)	Chi-square p-value
Age (years)*	62.8	57.8	0.001
Women	26.0%	33.0%	0.258
Diabetes	47.6%	45.4%	0.750
Hypertension	67.2%	67.0%	0.983
Dyslipidemia	53.9%	48.8%	0.460
Tobacco use	62.5%	54.5%	0.242
Stent indication†			
– Angina	50 (41%)	44 (51%)	0.793
– Previous MI	36 (30%)	16 (18%)	
– Recent MI (< 30 days)	36 (29%)	27 (31%)	
Number of vessels treated			
– 1 vessel	112 (88%)	77 (86%)	0.29
– 2 vessels	15 (12%)	12 (14%)	
Number of stents			
– 1 stent	89 (70%)	64 (74%)	0.529
– 2 stent	32 (25%)	18 (20%)	
– 3 stent	7 (5%)	5 (6%)	
Average number of stents	1.36 (95% CI; 1.26-1.47)	1.32 (95% CI: 1.18-1.47)	

*T-test with equal variances assumed was used to verify whether the age difference between the two groups was significant. Chi-square test was used to test proportions differences in all the other patient characteristics variables.
†We used the independent tests of chi-square for categories (stent indication, number of vessels and number of stents) and the type of stent used.
MI: myocardial infarction.

The cost category with the largest contribution to the total costs for the two groups was hospitalization, followed by intensive therapy. Information on the unitary costs of the stents used in the analysis suggested that the EGDESs and NGDESs were significantly more expensive than the BMSs.

The results for base-case scenario indicated that the expected costs of the EGDESs and NGDESs alternatives were 1.89- and 2.17-fold higher than those of the BMSs, respectively (Table 4). Average cost-effectiveness ratios for the EGDESs and NGDESs when compared with the BMS were 1.62 and 1.88, respectively (Table 4). The estimated incremental cost-effectiveness ratios suggest that EGDESs (US$ 28,910) and NGDESs (US$ 35,595) were significantly higher compared with BMS. In addition, results suggest that the incremental cost-effectiveness ratio of changing from old to new technology is significantly more expensive (US $84,983) (Table 4).

Our one-way deterministic sensitivity analysis results suggested that in the best scenario, when the MACE risks of EGDESs and NGDESs were lower than those in the base-case scenario, the incremental costs per MACE and incremental cost-effectiveness ratio represents a reduction of 14 and 29% of the base-case estimates, respectively (Table 4). In the worst scenario, the incremental cost-effectiveness ratios compared

Table 4. Cost-effectiveness in base-case and sensitivity analysis of stents (to test changes in major adverse cardiac event risk and their effect on incremental cost-effectiveness ratios)

Base-case cost-effectiveness results						
Alternative	**Costs***	**Effectiveness***	**Incremental costs†**	**Incremental effectiveness**	**ACER**	**ICER**
BMS	3,717	0.80100			4,640	
EGDES	6,838	0.90895	3,121	0.1080	7,523	28,910
NGDES	8,079	0.92356	4,362	0.1226	8,748	35,591
NGDES-EGDES			1,241	0.0146		84,983
One-way sensitivity analysis results						
Scenarios/alternatives compared	**Risk values**		**Incremental costs***	**Incremental effectiveness**		**ICER[1]**
Base case scenario						
– EGDES vs. BMS	BMS = 0.1990		3,121	0.1080		28,910
– NGDES vs. BMS	EGDES = 0.0910		4,362	0.1226		35,591
– NGDES vs. EGDES	NGDES = 0.0764		1,241	0.0146		84,983
Best scenario						
– EGDES vs. BMS	BMS = 0.1990		2,989	0.1206		24,776
– NGDES vs. BMS	EGDES = 0.0783		3,991	0.1580		25,262
– NGDES vs. EGDES	NGDES = 0.0410		1,003	0.0374		26,829
Worst scenario						
– EGDES vs. BMS	BMS = 0.1990		3,228	0.0977		33,042
– NGDES vs. BMS	EGDES = 0.1013		4,522	0.1073		42,155
– NGDES vs. EGDES	NGDES = 0.0917		1,294	0.0096		135,206
Threshold scenario (extreme values of NGDES risks as cost-effective as EGDES)						
– EGDES vs. BMS	BMS = 0.1990		3,122	0.1079		28,930
– NGDES vs. BMS	EGDES = 0.0911		4,141	0.1437		28,827
– NGDES vs. EGDES	NGDES = 0.05534		1,020	0.0358		28,517

*Costs are in USD (2014). Effectiveness was estimated as 1-probability of a major adverse cardiac event.
†Incremental costs and effects of DESEG and DESNG are estimated by comparison to BMS.
ACER: average cost-effectiveness ratio; ICER: incremental cost effectiveness ratio; BMS: bare-metal stent; DES: drug-eluting stent; EGDES: early-generation drug-eluting stent; NGDES: new-generation drug-eluting stent.

with the base-case scenario were more than 14 and 18% for EGDESs and NGDESs, respectively.

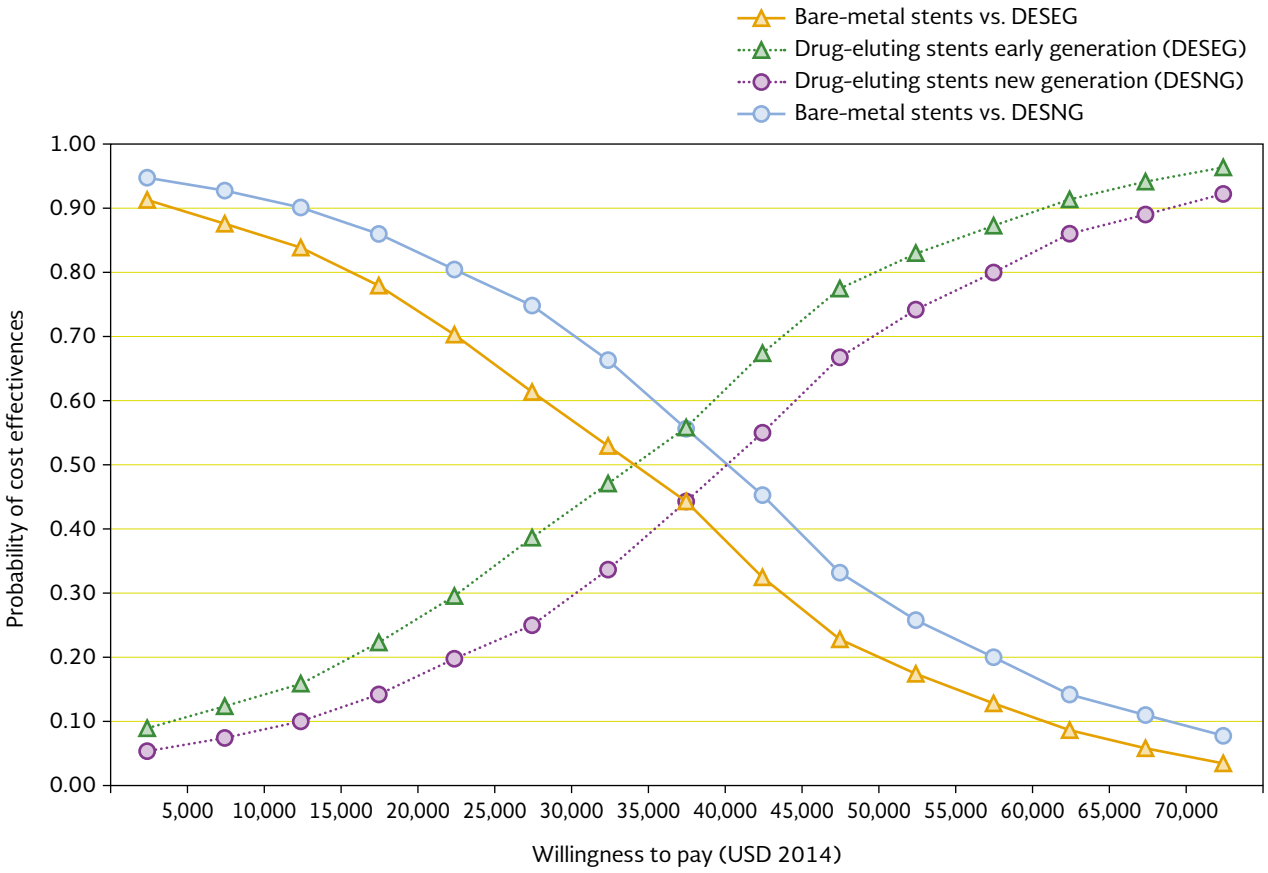
The results of our probabilistic sensitivity analysis also suggested that the percentage of being cost-effective was 90% of the cases when the willingness to pay was US$ 58,000 for EGDESs and US$ 66,000 for NGDESs, compared to BMSs (Fig. 1).

DISCUSSION

The research conducted estimated the cost of preventing subsequent MACEs in one year of follow-up for patients who had suffered an ischemic cardiomyopathy that required angioplasty. If the risk is lower, as in the best scenario, the cost per MACE may decrease by 29% when using the assumed value of 0.0410 for NGDESs. This risk reduction may correspond to a good selection of patients with the appropriate characteristics, which may maximize health benefits[14]. Resources associated with the use of stents can be employed efficiently in patients who have more favorable characteristics of cardiovascular lesion. In the best scenario, it is better to have larger vessels affected, smaller lesions, and non-diabetic patients. In addition to the selection of patients, another scenario that may be efficient is that the number of stents to be used per angioplasty should be less than three, with a higher frequency of them concentrated in the use of one and two stents.

In the worst scenario, the cost of the NGDES alternative may increase by 18%; therefore, the uncertainty appears to be high. The recommendation that derives from our study is that a larger sample should be considered for collecting more precise information regarding the factors modifying MACE costs. In addition, information on the risk for local patients considering their health status and risk factors obtained with a

Figure 1. Cost-effectiveness acceptability curve for early and new-generation drug-eluting stents compared with bare-metal stents.



large sample of patients may also help to determine more precise incremental cost-effectiveness ratio estimates.

Some evidence has suggested that factors such as the number of vessel lesions, number of segments treated, and length of the stent may not have a significant effect on the incremental cost-effectiveness ratio. This conclusion was made by the authors who measured and included a statistical analysis for the purpose of estimating the cost-effectiveness of EGDESs[20]. Our main conclusion based on results of this study is that incremental cost-effectiveness ratio estimates of NGDESs are higher than those of EGDESs when considering BMS as a common comparator. The results of our study suggest that the investment in EGDESs and NGDESs is value-for-money when the willingness to pay is above US$ 40,000 per MACE. An estimate of the cost per MACE that is reasonable is not available for a country like Mexico. A translation of the cost per MACE could be made considering the number of years that one MACE may extend the life and the quality of life of the average patient. If we consider that this is between three and five years, the cost per MACE using EGDESs and NGDESs may represent a reasonable investment. Another research problem that is necessary to investigate is the willingness to pay level (or the range) for investing in cardiovascular interventions. In the case of low-resource settings, our probabilistic sensitivity analysis suggests that BMS may be a better investment since the probability of being cost effective is higher for these stents compared with EGDESs and NGDESs.

Incremental cost-effectiveness ratio estimates considering MACEs as an outcome have been reported in other studies. Our base-case incremental cost-effectiveness ratio estimates seem to be below those in settings from high-income countries such as the USA and the UK[21,22]. Estimated differences may be a result

of differences in methodology, comparators, and prices of stents, or of the period during the follow-up of patients for considering the costs and number of events averted.

The use of a MACE as an outcome in this study makes it difficult to conduct a comparison with larger numbers of other studies. Authors who have reviewed stent cost-effectiveness studies found that only three out of 16 investigations reported the cost per MACE averted[23]. In this regard, the recommendation should be followed in future studies to include a standard measure as a quality adjusted life year for comparison.

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